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14. ABSTRACT
Purpose: The study compared two approaches to prosthetic rehabilitation treatment in military

personnel with a unilateral trans-tibial amputation (TTA). Design: A randomized control design assessed the effects of adding a home-based neuromuscular electrical stimulation (NMES) protocol to the standard prosthetic rehabilitation protocol. Methods: Participants in the NMES group received 12 weeks of electrical muscle stimulation 15-20 min/day, 5 days a week. Both groups received a 12-week standard Amputee rehabilitation protocol. The aims were to compare the two groups on: knee muscle strength; functional performance (mobility), QOL; and symptoms associated with residual and phantom limb pain. Sample: 45 subjects aged 18-55 yrs with traumatic TTA were randomly assigned to nurse-managed NMES Rehabilitation Program (n=23) or standard Amputee Protocol (n=22). Analysis: Linear mixed models compared the outcomes of both groups after 3, 6, 9 and 12 weeks. Multiple linear regression analysis was used for functional performance with 2 time points (after 6 and 12 weeks). Findings: Acceptance of the nurse-managed program was good as withdrawal rates were similar for both groups. No differences were found between the groups for any outcome measurement. Both groups showed improvement in strength in the amputated extremity, in functional performance, and in self-perception of functional capability. Implications for Military Nursing: Pain and reduced mobility are major problems for injured TTA warriors. The study examined a potentially useful intervention for our war fighters with a battle-related amputation by combining a nurse-managed NMES home-based program with in-clinic physical therapy. The goal of the nurse-managed program was to promote adherence, increase quality of life, enhance continuity of care, and promote better outcomes. The addition of the home-based program was well accepted, did not adversely impact rehabilitation and may represent a useful addition for some individuals. However, the study did not demonstrate quicker recovery as compared to in-clinic physical therapy.

15. SUBJECT TERMS

prosthetic rehabilitation treatment, unilateral trans-tibial amputation, nurse-managed NMES home-based program,in-clinic physical therapy

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Abstract

Purpose: The study compared two approaches to prosthetic rehabilitation treatment in military personnel with a unilateral trans-tibial amputation (TTA).

Design: A randomized control design assessed the effects of adding a home-based neuromuscular electrical stimulation (NMES) protocol to the standard prosthetic rehabilitation protocol.

Methods: Participants in the NMES group received 12 weeks of electrical muscle stimulation 15-20 min/day, 5 days a week. Both groups received a 12-week standard Amputee rehabilitation protocol. The aims were to compare the two groups on: knee muscle strength; functional performance (mobility), QOL; and symptoms associated with residual and phantom limb pain.

Sample: 45 subjects aged 18-55 yrs with traumatic TTA were randomly assigned to nurse-managed NMES Rehabilitation Program (n=23) or standard Amputee Protocol (n=22).

Analysis: Linear mixed models compared the outcomes of both groups after 3, 6, 9 and 12 weeks. Multiple linear regression analysis was used for functional performance with 2 time points (after 6 and 12 weeks).

Findings: Acceptance of the nurse-managed program was good as withdrawal rates were similar for both groups. No differences were found between the groups for any outcome measurement. Both groups showed improvement in strength in the amputated extremity, in functional performance, and in self-perception of functional capability.

Implications for Military Nursing: Pain and reduced mobility are major problems for injured TTA warriors. The study examined a potentially useful intervention for our war fighters with a battle-related amputation by combining a nurse-managed NMES home-based program with in-clinic physical therapy. The goal of the nurse-managed program was to promote adherence, increase quality of life, enhance continuity of care, and promote better outcomes. The addition of the home-based program was well accepted, did not adversely impact rehabilitation and may represent a useful addition for some individuals. However, the study did not demonstrate quicker recovery as compared to in-clinic physical therapy.

TSNRP Research Priorities that Study or Project Addresses

Primary Priority

Force Health Protection:	☐ Fit and ready force ☒ Deploy with and care for the warrior ☐ Care for all entrusted to our care
Nursing Competencies and Practice:	☐ Patient outcomes ☐ Quality and safety ☐ Translate research into practice/evidence-based practice ☐ Clinical excellence ☐ Knowledge management ☐ Education and training
Leadership, Ethics, and Mentoring:	☐ Health policy ☐ Recruitment and retention ☐ Preparing tomorrow's leaders ☐ Care of the caregiver
Other:	☐

Secondary Priority

Force Health Protection:	☐ Fit and ready force ☐ Deploy with and care for the warrior ☒ Care for all entrusted to our care
Nursing Competencies and Practice:	☐ Patient outcomes ☐ Quality and safety ☐ Translate research into practice/evidence-based practice ☐ Clinical excellence ☐ Knowledge management ☐ Education and training
Leadership, Ethics, and Mentoring:	☐ Health policy ☐ Recruitment and retention ☐ Preparing tomorrow's leaders ☐ Care of the caregiver
Other:	☒ Casualty Care

Progress toward Achievement of Specific Aims of the Study or Project

Findings related to each specific aim, research or study questions, and/or hypothesis

A. Brief Description of Research Design

We used a randomized controlled trial design to assess the effects of adding a home-based 12-week neuromuscular electrical stimulation (NMES) protocol to the standard prosthetic rehabilitation protocol in wounded warriors with a traumatic trans-tibial amputation (TTA). The specific aims were to test a home-based nurse-managed neuromuscular electrical stimulation (NMES) protocol as a supplement to usual rehabilitation (treatment group) relative to usual rehabilitation (standard of care group) by comparing: (1) lower extremity muscle strength (Specific Aim 1); (2) functional performance of daily activities after prosthetic fitting (Specific Aim 1); (3) quality of life (QOL) (Specific Aim 2); and (4) symptoms associated with residual and phantom limb pain (Specific Aim 2).

The final group of subjects consisted of 45 of the 48 soldiers with a single trans-tibial amputations (TTA) who enrolled in the study and were randomized to either the traditional (N=22) or NMES (N=23) treatment. Three subjects enrolled but withdrew before any testing took place. The baseline demographic characteristic for the 45 subjects is given in Recruitment and Retention Table. The majority of the subjects were active duty enlisted men in their twenties at the time of study entry with the primary service being Army. Most of the subjects had amputations within 30 days of injury and entered the study within a median of 43 days from amputation. The two treatment groups did not differ on these characteristics.

The study was a 12-week intervention with multiple testing visits. Eighty-four percent of subjects completed seven weeks of the study and sixty-four percent of the subjects completed the 12 weeks of the protocol. The dropout rate was similar for both treatment groups.

For Specific Aims, except for functional performance of daily activities, outcome measures were examined up to 5 times over the 12 weeks of the study. For these aims a generalized mixed effects model was applied with a random effect for subject. Time was a fixed effect for the weeks where the testing was completed. The random effect considers the within subject correlation of data across the time of the study and considers the amount of data collected with weighting for missing/incomplete data. Two models were compared in the analyses to test whether the two treatments differed across time in study: (1) the first model included time and treatment group; (2) the second model included model 1 plus the interaction between time and treatment group. The two models were compared using a likelihood ratio test.

Analyses to address functional performance of daily activities required a different approach. The functional measurements (distance walked in 2-minutes, time to complete an “up-and-go” test, a timed stair climb, and the number of stands during a 30-second chair rise test) were dependent on the soldier having the prosthesis for the amputated limb which typically occurred by week 7 of the study. The functional tests were measured at the 7 and 13 week visits. These measurements were examined using a linear regression model with the 13 week measurement as the outcome variable regressed on for the 7 week measurement and the treatment group.

B. **<u>Specific Aim I</u>: *To test the* effectiveness of a nurse-managed NMES rehabilitation program as compared to the standard of care Amputee Protocol, for improving lower extremity muscle strength and mobility**

Muscle strength was measured with a handheld dynamometer for extensor and flexor knee strength of the residual and intact limb. *Mobility* was measured by the distance walked in 2-minutes, time to complete an "up and go" test, a timed stair climb and number of stands during the 30-second chair rise test. Knee extensor strength in the amputated leg was low relative to the intact extremity at baseline in both treatment groups. Over the course of the study, the amputated extremity showed increased knee strength so that by the end of the study, both the amputated and intact extremities were similar in strength. The improvement in knee extensor strength was observed in both treatment groups with no evidence for a difference in the rate or extent of improvement between the two treatments. The strength in the intact leg remained constant over the course of the study. Similar findings were observed in relationship to knee flexor strength with no differences found between the two treatment groups.

Mobility was measured after week 6 and week 12 study visit. No differences in improvement over time were observed in the distance walked in 2-minutes, the "up and go" test, and the timed stair climb between the two treatment groups. The number of chair stands in 30 seconds trended to differ between the two treatments across the 7 and 13 week measurement—with the traditional physical therapy treatment group increasing the number of chair stands by 4, while the NMES group increased by 2 chair stands.

C. **<u>Specific Aim II</u>: *To determine* if the nurse-managed NMES rehab program is more effective for improving QOL and symptoms associated with residual limb and phantom pain as compared to standard of care Amputee Protocol**

QOL was measured by responses to the Medical Outcome Questionnaire and the Centers for Epidemiologic Studies-Depression scale. *Symptoms* were quantified by the McGill Pain Questionnaire with the Visual Analog Scale. The Medical Outcome Questionnaire (MOQ) was administered at 3 visits: baseline, and after week 6 and week 12. The questions query amputees' self-perception of both physical and mental status. The questionnaire has been well validated to represent 8 scales that characterize mental and physical status. The data can be analyzed by the scale directly; further the scale has been normalized by Ware et al. (1992) resulting in data with more parametric characteristics. Three of the 8 scales showed improvement over the 12 weeks of the study across all subjects with no difference based on treatment. The three scales included physical functioning, role-physical and body pain. The largest change was in the self-perception of physical function, with lesser changes in concept of what could physically be performed and in reduction in pain perception. Mental health measures did not change over the 12 weeks. Likewise, no change in the Centers for Epidemiologic Studies-Depression Scale was observed over the course of the study for either treatment group. Similarly, no change in current pain levels as assessed by the McGill Pain Questionnaire was observed in either group during the study.

In summary, the study found that the home-based nurse-managed NMES protocol was well received by the research subjects who used the NMES units regularly as prescribed by the protocol. Outcomes for the two treatment groups were found to be equivalent, but the sample size recruited was not as large as planned and may have been underpowered to demonstrate a true difference in the two groups. What was observed was that over the course of the study, both treatment groups improved muscle strength in their amputated legs to levels similar to their intact legs. With the increase in strength, an improvement in the functional mobility measurements was also observed. Associated with these

changes was an improvement in self-perception of physical status as measured by the MOQ. This improvement was not associated with an improvement in mental health.

Relationship of current findings to previous findings

Specific Aim 1

We found that a home-based neuromuscular electrical stimulation (NMES) protocol was as effective as usual care for strengthening quadriceps femoris muscle in traumatic unilateral trans-tibial amputation. We are unaware of other studies that have studied the use of NMES in the treatment of lower extremity amputations. NMES has been shown to be an effective alternative or addition to traditional strength training in both trained and elite athletes (Filipovic, Kleinoder, Dormann, & Mester, 2012) and thus seemed a potentially beneficial treatment for our wounded warriors. NMES has been shown to be a useful addition to rehabilitation in traumatic injuries to the knee, particularly in arcuate ligament injury repairs (Imoto, Peccin, Almeida, Saconato, & Atallah, 2011; Snyder-Mackler, Delitto, Bailey, & Stralka, 1995). With both amputation and anterior cruciate ligament (ACL) injuries, there is a major decline in usage of the injured extremity following the injury that over a short period of time results in disuse atrophy with accompanying loss of strength and function. Unilateral TTAs experience significant reductions in thigh muscle strength of the amputated limb during the first year after amputation. The residual limb is less active in daily functions of standing and walking, resulting in progressive atrophy of the quadriceps muscles in terms of a decrease in thigh diameter which is estimated at 25% of pre-amputation diameter. Disuse atrophy has been of concern in other situations; e.g., with the astronaut program in association with prolonged space flight with accompanying loss of gravity. NASA has completed studies demonstrating that NMES can slow the disuse process in volunteers subject to prolonged bed rest (Duvoisin, Convertino, Buchanan, Gollnick, & Dudley, 1989). A recent study has demonstrated that men with acute spinal cord injuries respond to NMES with increase in quadriceps size rather than atrophy (Arija-Blázquez et al.).

What was particular unique in this study was the addition of nurse-managed home-based stimulation to standard clinic-based rehabilitation. Reports of the use of home-based NMES are few. We first reported a home-based nurse-managed program for the treatment of knee OA (Talbot, Gaines, Ling, & Metter, 2003). Subsequently, Bruce-Brand et. al. (2012) recently confirmed our findings with home-based NMES in patients with moderate to severe knee OA. Other studies have demonstrated that NMES can be effective in improving strength and function in OA patients using clinic-based programs when administered in singly or in combination with other rehabilitation (Takano et al., 2010; Vaz et al., 2013).

Specific Aim 2

Our study looked at wounded warriors' self-perception of their health during a period of rehabilitation. During these 12 weeks, a clear improvement was observed in self-perception of physical status as measured by the MOQ, but not in mental health. The improved self-perception of physical status parallels receiving a prosthesis, improvement in strength in the amputated leg, and better functional performance. The lack of change in mental health as measured by the MOQ is likely related to at least three factors: (1) these wounded warriors at entry into the study had mental health scores that were high relative to the general population of their age, (2) while they show good improvement in their functional performance, the improvements are not to the level of function pre-amputation, and (3) the persistence of pain. We are aware of only one report that examines the rehabilitation of wounded warrior following injury: a case study of a double amputee that described the processes and issues that this soldier had to face in returning to the community (Goff, Bergeron, Ganz, & Gambel, 2008). Several studies have examined the long term outcome for traumatic amputees, but these observations are not

directly related to the period of rehabilitation at the time of receiving a prosthesis (Penn-Barwell, 2011). Of note, a long term follow-up of above-the-knee bilateral amputees from the Viet Nam conflict found the persistence of low physical function score on the MOQ but subjects were noted to have had a relatively productive and normal life when considering their functional limitations on average 27.5 years following injury (Dougherty, 1999). Another study examined the time period when wounded warriors were admitted to the acute care hospital to treat injuries from improvised explosive devices (Benfield et al., 2012). The persistence of pain and residual problems associated with amputation, associated traumatic brain injuries and other problems occurring in wounded warriors has led to the developments of Polytrauma Rehabilitation Centers by the Department of Veterans Affairs, which are offering pain and family related programs (Clark, Bair, Buckenmaier III, Gironda, & Walker, 2007; Collins & Kennedy, 2008).

Effect of problems or obstacles on the results

This study was designed as a multi-site randomized trial to promote timely recruitment, enhance generalization, and increase statistical power. The initial study sites identified were Walter Reed Army Medical Center (WRAMC), Washington, DC and Brook Army Medical Center (BAMC), San Antonio. To minimize site variance, we used checklists, standard operating procedures, and regular tester/trainer check-offs to standardize the intervention and data collection procedures. At the university site, the college of nursing provided data management and monitored the information received from the study sites. There was variation in usual care at the clinical sites with therapists making individualized treatment decisions. Participants varied from site-to-site based on multiple co-morbidities and secondary complications associated with their blast injuries.

BAMC site: Walter Reed Army Military Center (WRAMC) was meeting recruitment goals; however, after one year of recruitment at BAMC, we were not able to recruit a sizable sample at this site. This was partially due to limited access and support from the Center for the Intrepid. Difficulties in participant accrual led to the decision to move from BAMC to Naval Medical Center, San Diego (NMCSD) and to maintain the WRAMC site.

WRAMC site: WRAMC moved to the new Walter Reed National Military Medical Center (WRNMMC) at Bethesda, Maryland, formally known as National Naval Medical Center, on August 24, 2011. The change in facility affected several aspects of recruitment, including IRB approval, which adversely affected recruitment for close to six months.

NMCSD site: After 1 year of seeking administrative approvals at NMCSD, we started recruitment. We received site approval June 2011. The subsequent site set-up and hiring of a research nurse was completed in October 2011, however, IRB approval to add the research nurse to the study personnel was not approved until December 2011. We were unable to begin recruitment at the NMCSD site until December 2011. We recruited 2 participants during January and February 2012, but did not recruit another participant until June 2012. Due to low recruitment at the NMCSD site, recruitment was stopped and participants in the study completed the 12-week intervention. We closed the site the end of September 2012.

The WRAMC move and issues in establishing an active recruitment program at NMCSD resulted in the study being underpowered to address the research aims as estimated in the original application. The final sample could reasonably test for a very large effect between the nurse-managed NMES and the standard Amputee Protocol, while the study was originally powered for a somewhat smaller effect.

Strengths and Limitations

The strength of this study was the use of a randomized controlled design to demonstrate the effects of two approaches to rehabilitation. The chosen outcome measurements are known to be valid predictors of mobility status and the level of functional disability, factors critical to the best outcomes for amputees. The study was able to address both Specific Aims; however, the study was not powered to detect a small or moderate difference between the two treatment groups.

Conclusion

The study clearly demonstrated that a nurse-managed home-based NMES program can be implemented in a military hospital environment. The program can be utilized in combination with more traditional rehabilitation programs for amputees. Participants who were randomized to the nurse-managed NMES protocol used the NMES units regularly as prescribed by the protocol. Outcomes for the two treatment groups were similar, with both treatment groups improving muscle strength in their amputated legs to levels similar to their intact legs. Improvement was seen in the functional mobility measurements, and improvement in self-perception of physical but not mental health status on the Medical Outcomes questionnaire.

Significance of Study or Project Results to Military Nursing

Nurse-Managed Home-based NMES Programs

Home-based amputee rehabilitation is a promising approach to traditional clinic-based rehabilitation. We used a home-based NMES strength program for the rehabilitation of TTA as a supplemental to the in-clinic physical therapy rehabilitation that was managed by nurses. Participants assigned to the home-based NMES group received individualized education, weekly reinforcement phone calls/texts, frequent reeducation, and adherence monitoring in addition to their physical therapy visits. Those assigned to the standard of care received traditional clinic-based amputee rehabilitation only.

Nurse-managed programs have been shown to promote adherence, increase quality of life, improve chronic pain, enhance continuity of care, and promote better patient outcomes. Nurse-managed programs that combine standardized protocols, telephone communication, and clinic or home visits have been successful in multiple patient populations: lower limb amputees, patients following trauma and heart failure patients.

The need for nurse managers is very evident at WRAMC/WRNMMC outpatient services. With the rapid incoming of wounded, WRAMC/WRNMMC had difficulty in tracking OEF/OIF outpatients. A Pentagon Independent Medical Review Group (IRG) found that wounded troops received excellent care until they were released from the hospital and in need of outpatient services. The IRG recommended a nurse case manager. The role of WRAMC/WRNMMC nurse managers was limited to coordination of services, assisting with the medical board (MEB) processes and follow-up. We proposed a nurse manager whose role would be to take an active part in the intervention. The nurse manager provided frequent reeducation, reinforcement, and encouragement, as well as training in NMES self-management and self-monitoring. Additionally, the nurse employed various means to support program adherence at home, including family involvement. To our knowledge, this project was the first randomized, controlled clinical trial of nurse-managed care in the rehabilitation of amputees.

The current study was novel by combining nurse management with home-based NMES with traditional physical therapy in the rehabilitation of TTA. Previous studies of individuals with TTA have been of elderly, vascular disease and diabetic patients whose functional outcome is “minimal ambulation.” The young, war-related TTA patients have very different expectations for future function and prosthetic performance. Given the extent of functional loss and warrior incapacity any treatment that improved muscle strength, functional performance of standing, walking and stair climbing, pain and QOL would contribute to improved rehabilitative outcome. The current study could not demonstrate an advantage of the nurse management program, but there was no evidence for a disadvantage. The study demonstrated that a nurse-managed program can be integrated with a standard clinic-based physical therapy/rehabilitation program in the rehabilitation of TTA.

Changes in Clinical Practice, Leadership, Management, Education, Policy, and/or Military Doctrine that Resulted from Study or Project

There appears to have been a change in clinical practice from the perspective of the patient. Following completion of the study, several participants in both groups requested NMES units from their health care providers. There appeared to be some perceived benefit in regards to pain, strength, and/or function by the amputees that they wanted to continue with the treatment.

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Summary of Dissemination

Type of Dissemination	Citation	Date and Source of Approval for Public Release
Publications		
Publications in Press		
Published Abstracts		
Podium Presentations		
Poster Presentations		
Media Reports		
Other		

Reportable Outcomes

Reportable Outcome	**Detailed Description**
Applied for Patent	None
Issued a Patent	None
Developed a cell line	None
Developed a tissue or serum repository	None
Developed a data registry	None

Recruitment and Retention Table

Recruitment and Retention Aspect	Number
Subjects Projected in Grant Application	60
Subjects Available	
Subjects Contacted or Reached by Approved Recruitment Method	96
Subjects Screened	96
Subjects Ineligible	10
Subjects Refused	38
Human Subjects Consented	48
Subjects Intervention Group / Control Group*	23/22
Intervention Group / Control Group Subjects who Withdrew	9/7
Intervention Group / Control Group Subjects who Completed Study	14/15
Intervention Group / Control Group Subjects with Complete Data	14/15
Intervention Group / Control Group Subjects with Incomplete Data	9/7

*3 subjects signed the consent and did not enroll into the study

Baseline Demographic Characteristics of the Sample

Characteristic	
Age (yrs)	26.64 ±5.99
Women, n (%)	1 (2.2)
Race	
White, n (%)	36 (80.0)
Black, n (%)	3 (6.7)
Hispanic or Latino, n (%)	1 (2.2)
Native Hawaiian or other Pacific Islander, n (%)	0 (0)
Asian, n (%)	1 (2.2)
Other, n (%)	4 (8.9)
Military Service or Civilian	
Air Force, n (%)	1 (2.2)
Army, n (%)	31 (68.9)
Marine, n (%)	10 (22.2)
Navy, n (%)	3 (6.7)
Civilian, n (%)	0 (0)
Service Component*	
Active Duty, n (%)	41 (91.1)
Reserve, n (%)	0 (0)
National Guard, n (%)	3 (6.7)
Retired Military, n (%)	N/A
Prior Military but not Retired, n (%)	N/A
Military Dependent, n (%)	N/A
Civilian, n (%)	N/A

*Data on Service Component missing on 1 subject.

Final Budget Report

The official final signed budget from University of Tennessee Health Science center is attached.